K061228 MAY 26 2006

510(k) Summary

Full Breath Sleep Appliance Anterior Bite With Posterior Tongue Depressor
Full Breath Sleep Appliance Posterior Bite With Posterior Tongue Depressor

Applicant

Bryan Keropian DDS
18607 Ventura Blvd., Suite 206
Tarzana, CA 91356

Product Name

Full Breath Sleep Appliance Anterior Bite With Posterior Tongue Depressor
Full Breath Sleep Appliance Posterior Bite With Posterior Tongue Depressor

Proposed Product Code

LQZ

Proposed Device Classification

Jaw Repositioning Device

Contact Person

Bryan Keropian DDS
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Telephone

W – 818-881-7233
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Fax

818-881-7541

510(k) Application Preparation

Bryan Keropian, DDS

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510(K) Summary (continued)

For the treatment of mild and moderate OSA, the Full Breath Sleep Appliance With Posterior Tongue Restrainer is substantially equivalent (SE) to the Quiet Night & Quiet Night MA (K032410), The Full Breath Sleep Appliance Anterior Bite With and Without Bumps (K052862), and the Full Breath Sleep Appliance Posterior Bite With and Without Bumps (K053065)

For the treatment of snoring, the Full Breath Appliance With Posterior Tongue Restrainer is SE to the Quiet Night & Quiet Night MA (K032410), The Full Breath Sleep Appliance Anterior Bite With and Without Bumps (K052862), and the Full Breath Sleep Appliance Posterior Bite With and Without Bumps (K053065), the Breathe EZ Anti-Snoring Device (K022891), the SleepBite (K103808), and Dr. B's Mouthpiece (K991948).

For the treatment of bruxism, the Full Breath Sleep Appliance is SE to the NTI Tension Supression System (K010876), the Breathe EZ Anti-Snoring device (K022891), the SleepBite (K103808). And Dr. B's Mouthpiece (K991948).

Product Name	Full Breath Sleep Appl. FBAB&FBPB	Quiet Night Quiet Nt. MA	NTI Tension Suppression System	Breathe EZ Anti-Snoring Device	Sleepbite	Dr. B's Mouthpiece
510(k)	K052862 K053065	K032410	K010876	K022891	K103808	K991948
Product Code	LQZ	LQZ	LQZ	LRK	LRK	LRK
Indicated Use	Treatment of Mild & Mod. OSA --	Treatment of Mild & Mod. OSA --	Prophylactic treatment of medically diagnosed migraine pain --			
	Treatment of Snoring --	Treatment of Snoring		Treatment of snoring --	Treatment of snoring --	Treatment of snoring --
	Prevent Bruxism	Prevent Bruxism	Prevent Bruxism	Prevent Bruxism	Prevent Brusxism	Prevent Bruxism
Method of Delivery	By prescription	By prescription	By prescription	By prescription	By prescription	By prescription

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 26 2006

Dr. Bryan Keropian
Bryan Keropian, DDS
18607 Ventura Boulevard, Suite 206
Tarzana, California 91356

Re: K061228
Trade/Device Name: Full Breath Sleep Appliance with Posterior Tongue Depressor
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: LQZ
Product Code: II
Dated: May 2, 2006
Received: May 2, 2006

Dear Dr. Keropian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061228

Indications for Use

510(k) Number (if known):

Device Name: Full Breath Sleep Appliance With Posterior Tongue Depressor

Indications For Use:

1. Full Breath Sleep Appliance With Posterior Tongue Depressor– This appliance is indicated for the treatment of snoring.
2. Full Breath Sleep Appliance With Posterior Tongue Depressor – This appliance is indicated for the treatment of mild to moderate obstructive sleep apnea.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) 15
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K061228